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TITLE: A Randomized Controlled Trial (RCT) to Assess and Improve the Effectiveness of Post-deployment Screening for Mental Illness

PRINCIPAL INVESTIGATOR: Roberto A. Rona, PhD

CONTRACTING ORGANIZATION: King's College London
London WC2R 2LS

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14. ABSTRACT The primary aim of the study is to assess whether a post deployment screening would reduce the levels of mental illness and the secondary aim is to assess the health-seeking behavior in relation to screening. The study is a cluster RCT design and recruited subjects at platoon level (20-35 individuals) as the unit of randomization. There are 2 arms: a screening group and a control group. Both arms have completed the self-administered computerized assessment. Only the screening group will receive specific advice on help seeking related to the scores on the mental health measures. Baseline data collection began in October 2011 and finished in February 2013, using an offline computerized screening questionnaire to assess PTSD, depression, anxiety and alcohol misuse in troops returning from Afghanistan. We have recruited 8,673 service personnel into the study. Follow up data collection began in December 2012 and will continue until April 2014. We expect that this cluster RCT will offer a robust assessment of the impact of screening for military personnel.					
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INTRODUCTION

- Despite intense efforts to screen US military personnel for mental disorders following deployment, the prevalence of mental disorders continues to rise in the first year after deployment. There have been calls in the UK to introduce similar post-tour screening in spite of a lack of evidence of its effectiveness.
- The main aim of this cluster randomized controlled trial (RCT) is to assess whether a post-deployment screening program for PTSD, depression, anxiety and alcohol misuse is effective in reducing the morbidity and functional impairment from these conditions.
- Secondary aims are to assess the subsequent health-seeking behavior of those identified as cases in the screened group in comparison to the control group.
- The study design is a cluster RCT, based on platoon (20-35 individuals) as the unit of randomization, which includes 8,673 service personnel in 2 arms: a screening group (aiming to include 66% of the total group) and a control group (33% of the total group). Both arms will complete the self-administered assessment. The screening group received specific advice related to their mental health scores but the control group only received general advice on help seeking in the military.
- We expect that this cluster RCT will offer a robust assessment of the impact of screening using a computer-based tool on mental illness in the military. We also expect that an effective screening program will improve the psychological welfare of personnel and thus contribute to force resilience and preparedness.

BODY

Task 1: Development of an offline mental ill health assessment tool

STATUS: Completed

The screening tests selected for the study were: the Post-traumatic Stress Disorder (PTSD) Checklist (PCL); the Brief Patient Health Questionnaire (PHQ-9); Generalized Anxiety Disorder questionnaire (GAD) and the Alcohol Use Disorders Identification Test (AUDIT). As indicated in our protocol the assessment is based on a two stage approach, a short test for each type of disorder and the full version of the PCL, PHQ-9, GAD and/or AUDIT according to the positive results of the short tests . We use in the first stage appraisal the Primary Care PTSD (PC-PTSD); the first two items of the PGQ-9 and the GAD and the first two questions of the AUDIT questionnaire (initially four items but modified later on, see last paragraph of this section).

In addition we collect information for monitoring purposes on mild Traumatic Brain Injury (mTBI) and one question to assess functional impairment. We also collect Service-demographic data, and a 5 items health economic instrument (Euro Qual-5D) to generate quality of adjusted life years (QALYs). The screening procedure is implemented using an offline tool. Data collected is stored in two separate encrypted files on a secure server. One file includes the participant's personal identifiers and survey number, and another includes the survey number and the responses to the offline questionnaire.

Specific recommendations are generated as a result of the responses given to each of the screening tests for those in the intervention group and general advice for those in the control arm of the study. We ensured that the offline instrument was free of glitches, provided a high standard of security and confidentiality, and that information could be downloaded securely to our University server. In the process of developing the tests, we piloted the tool in-house to ensure correct functionality and ease of use.

We piloted the procedure in 99 Service personnel, all were private rank, to ensure that participants understood the items

of the screening tests, were able to navigate the system appropriately, and gained feedback from participants on advice provided to the screening and control group (June 2011). In 52 participants we obtained consent to ask for detailed feedback on the questionnaire and separately, for a qualitative study aimed to assess the views on a screening program for mental illness in the UK military.

After piloting we refined the online instrument to produce a full model of the tool which is used in the study both for those who will be in the intervention arm and those who will be part of the control arm. We decided to eliminate the first two questions from the post-deployment screening instrument used by the US Department of Defense in this part of the questionnaire as too many sub-threshold participants were completing the AUDIT. We re-piloted this modified questionnaire with 18 Royal Marines and 20 Reservists to assess understanding, acceptability and length. The tool was ready for use two months before the start of the main study.

Task 2: Recruitment and assessment of personnel in the initial assessment of the screening and control groups

STATUS: Completed

We randomized 437 PLATOONS into two groups and obtain informed consent from individuals for follow up and access to medical/personnel records. In the first wave of data collection, between October 2011 and February 2012, we screened 2,640 Royal Marines and Army personnel out of a maximum of 3,600. In the second wave of data collection between May and June 2012 we screened 3,300 out of a possible 3,500. In the third wave of data collection we screened 3034 out of an estimated preliminary total of 3,300 subjects in the selected platoons.

We provided those in the screening arm with advice according to test results immediately following questionnaire completion. The control group received general advice. Both groups received a letter by post within 2 weeks of completing the offline questionnaire. This letter reiterated the advice given on-screen during the assessment.

In February 2012 the USAMRMC granted permission to extend the period of recruitment of service personnel to the trial by a further 6 months. Our request followed a finding that 50% of

those in the screening arm of the study did not want to receive specific advice. This unexpected result would decrease the statistical power to detect a difference between the screening and control arms of the study. We changed the ratio of randomization between the intervention and the control arms in waves two and three of baseline data collection from 1:1 to 2:1; thereby increasing the number of tours included in the study from 2 to 3 (HERRICKS 14, 15 and 16). This increased the total number of service personnel in the study from 5,200 to approximately 8,673. We found that the percentage unwilling to receive tailored advice in tours 2 and 3 decreased to nearly 30% from 50% in tour 1. This trend towards an increase of the acceptability of tailored advice will also increase the contrast between the intervention and the control arms of the study. These proposed changes were agreed on 16 February 2012 by Dr Robert Linton, Chairman of the Ministry of Defence Research Ethics Committee (General).

A secondary aim of our study is to assess the health care seeking behavior of personnel in the screening and control arms of the study. This undertaking will be carried out obtaining information from those recruited in the study in the follow up stage and obtaining routinely collected information UK Defence Medical Information Capability Programme (DMICP) and the Joint Personnel Administration (JPA). DMICP has never been used in research until now and this intended use of the system is a major challenge. An assessment of suitable fields from the DMICP and the JPA databases has been successfully undertaken on pilot data and a Data Sharing Agreement between King's College and DASA was signed in August 2012.

Task 3: To reassess personnel in the two arms (17 months)

STATUS: Ongoing

The content of the follow-up questionnaire was finalized in January 2012. We developed three alternatives for the follow-up questionnaire: an offline questionnaire to use in personnel who remained in their original assessed unit, a pen and paper questionnaire and an online questionnaire which would allow for the completion of questionnaires anywhere in the world with an internet connection. The second and third options will be used in those who changed unit or left the services. was also developed. We envisage that we would have to make several attempts to contact a large proportion of the participants.

The suitability of offline, online, web-based and pen and paper follow-up questionnaires were piloted in May 2012 with a company from the Household Cavalry and ready by September 2012.

Our approach to data gathering in the follow-up stage was as follows: we firstly identify where our cohort is based, whether they have been discharged or posted to other units or still in their original unit. Where there are sufficient numbers, we will conduct base visits in order to follow up those still with their original units. We will use paper or web-based questionnaires for those who were unavailable during the visits, those who have left service and those who are in bases with a low number of participants.

The reassessment period will take up to 16 months in total for the three deployment groups. Approximately 15% to 20% of the participants may have left the Armed Forces and we will need to find valid contact details for many of them. The number of personnel we will follow up will include all randomized units and is likely to exceed 10,000 personnel. We are contacting those who did not complete a baseline questionnaire in the selected units to assess whether those who did not participated in the initial assessment were different to those who participated and also because we will include all those who provided data in the follow up stage of the study in the main analysis (intention to treat) and compare it to results of the analysis of those who participated in the baseline assessment only (treatment effect).

Linkage to personnel electronic data systems (JPA) has been successfully provided by DASA. We hope to get data from the DMICP database for the consenting participants for a period of 18 months pre-initial assessment and 18 months following initial assessment. A first test extract of DMICP data has been received by DASA in March 2013.

Task 4: Analysis and dissemination of main results

STATUS: Not yet started

KEY RESEARCH ACCOMPLISHMENTS

1. A versatile offline mental health screening assessment which offers immediate tailored advice has been successfully implemented in 8,673 Service personnel.
2. A fully proven system of entry of Service personnel into the study; first gaining chain of command support for the study, then preparing a fully identifiable set of companies and platoons for randomization on the day of assessment.
3. To set up in a remote location 45 laptops pre-loaded with the appropriate type of questionnaire (intervention and control versions), to minimize waiting time for participants and minimize errors of allocation i.e. personnel being presented with the correct version of the computerized questionnaire according to randomization.
4. To ensure the safe and secure return of data to research offices and to download data to the secure college server.
5. To send feedback letters to all trial participants within 2 weeks of completing the questionnaire.
6. To ensure the maximum response rate at follow up by using online, offline and pen and paper questionnaires obtained via a combination of face to face visits and email/postal reminders.

REPORTABLE OUTCOMES

We have published a qualitative study based on data collected in our study. *Contrasting beliefs about screening for mental disorders among UK military personnel returning from deployment to Afghanistan*. Journal of Medical Screening; November 2012.

Link to publication here:

<http://jms.rsmjournals.com/content/early/2012/11/05/jms.2012.012054.full.pdf>. See PDF attachment to email.

In addition, we have collected and transcribed data on another qualitative study, and are currently analysing it. The purpose of the study was to assess on healthcare providers' beliefs about screening in the uK Armed Forces. The researchers interviewed a total of 11 Medical Officers and 10 Unit Welfare Officers responsible for personnel who has just returned from a tour to Afghanistan.. Analysis is expected to be completed by June 2013 - see **APPENDIX 1** below for qualitative interview schedule.

CONCLUSIONS

Conclusions: As we have not finished the study we do not have results on its main outcomes. However, we have gained invaluable information on the way service personnel think and appraise the value of screening for mental illness in the service. If the study were to show that screening is effective we would be in position to advice on the organization of a screening program in the UK military. The study is on target as we have completed the recruitment stage (January 2013) and baseline assessment of individuals in the platoons entered into the study. We have started follow up data collection and expect this stage of the study to be challenging as a large percentage of service personnel have moved to another unit or have left the Armed Forces. However, we are cautiously optimistic because of the expertise gained by our research team.

We have just received the first test extract of DMICP data and hope that we will be able to utilise routinely collected medical and personnel data to assess the health care seeking behaviour of our cohort for research purposes.

REFERENCES

Keeling M, Knight T, Fertout M, Greenberg N, Chesnokov M, Rona RJ. The contrasting beliefs of screening for mental disorders in UK military personnel returning from deployment to Afghanistan. *J Med Screen* 2012;1-6
DOI: 10.1258/jms.2012.012054

APPENDIX 1:**QUALITATIVE INTERVIEW SCHEDULE**

- 1) *What are your experiences of seeing service personnel with mental health problems post-tour?*
- 2) *How do you feel about the current structure of mental health provisions and access to care?*
- 3) *What do you think are the current barriers for service personnel seeking care for mental illness?*
- 4) *How much of a problem do you think that stigma is for service personnel?*
- 5) *What do you think about post-tour screening?*
- 6) *What problems do you envisage for the provision of services if a screening programme for mental illness were implemented in the UK military?*
- 7) *How would screening impact on your working life?*
- 8) *If someone comes to you having been advised to do so following screening, how would you respond to this patient?*
- 9) *Overall, how do you feel about the potential introduction of post tour screening for mental health?*